

REMARKS

Applicants appreciate the courtesy shown by the Examiner in discussing this application with the undersigned on October 25, 2007. The above amendments and the following remarks reflect the discussions. Claim 1 has been revised editorially. Claim 2 has been canceled without prejudice or disclaimer. Claim 7 has been amended editorially, as supported at page 10, line 7.

The pending claims were rejected under 35 USC 112, first paragraph. Applicants respectfully traverse this rejection. The rejection seems to question the written description support in the specification for terms such as "composition" and "fine granules". Applicants note that the nature of "composition" as the portion in which the active ingredient is contained is clear in view of the discussion at page 13, line 23-25 and page 14, lines 28-33, as well as the discussion of the methods for formulating the "composition" beginning on page 25. The nature of the "fine granules" as including the "composition" and coating layer(s) is clear from the discussion at page 30, lines 1-11. Claim 1 has been revised editorially to characterize "composition" as "core composition" for convenience in identification. Since the specification discussed in detail that the "composition" in fact is coated to form the "fine granules", the identification of the "composition" as "core" is understandable. Applicants submit that the specification fully supports the invention as claimed and the rejection should be withdrawn.

The pending claims also were rejected as obvious over Lundberg in view of Watanabe and Murthy. Applicants respectfully traverse this rejection. The rejection contends that the present record does not establish adequately the significance of the presence of the coating layer of the fine granules (element (i)(c) in claim 1). Filed herewith is a Declaration by Dr. Shimizu, reporting additional experimental work. A comparison is made between a product in which the fine granules included the coating layer of mannitol (Formulation 2 and OD-2) and one in which the fine granules did not include the coating layer of mannitol (Formulation 1 and OD-1). Note that the total amount of mannitol in the two oral dosage units (OD-1 and OD-2) was the same – the only difference is that in OD-2 some of the mannitol was used to coat the fine granules. The results show that OD-2 enjoyed an increase in hardness of over 40%, and exhibited a friability that was more than an order of magnitude less than that of OD-1. At the same time, OD-2 showed excellent oral disintegration performance, well within the upper limit of one minute set forth in claim 1. Applicants respectfully contend that these results are more than adequate to

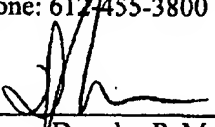
establish the unexpected advantages achieved by the use of the coating layer, particularly when considered in light of the other results of record as discussed in previous submissions.

In view of the above, Applicants request reconsideration of the application in the form of a Notice of Allowance. The Examiner is invited to contact the undersigned if any issues remain.

Respectfully submitted,

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